

PATENT COOPERATION TREATY PCT Rec'd P/PTO 0 7 06 T 2004

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 0 2 APR 2004

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Applicant's or agent's file reference PCT-7050	FOR FURTHER ACTION	HER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)				
International application No. PCT/IT 03/00214	International filing date (day/monto) 08.04.2003	th/year) Priority date (day/month/year) 09.04.2002				
International Patent Classification (IPC) or both national classification and IPC A61K31/205						
Applicant SIGMA-TAU HEALTHSCIENCE S.P.A. et al.						
 This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 						
2. This REPORT consists of a total of	of 4 sheets, including this cover	sheet.				
been amended and are the l	This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).					
These annexes consist of a total of	of sheets.					
3. This report contains indications re	lating to the following items:					
I ⊠ Basis of the opinion						
II ☐ Priority	•	, 5				
III D Non-establishment of o	opinion with regard to novelty, in	nventive step and industrial applicability				
IV Lack of unity of inventi	on					
V 🖾 Reasoned statement u citations and explanati	inder Rule 66.2(a)(ii) with regard ons supporting such statement	d to novelty, inventive step or industrial applicability;				
VI	ed					
VII	nternational application					
VIII Certain observations o	n the international application					
Date of submission of the demand	Date of	completion of this report				
10.10.2003		2004				
Name and mailing address of the international preliminary examining authority:	al Authoriz	zed Officer				
European Patent Office D-80298 Munich	Pacre	u Largo, M				
Tel. +49 89 2399 - 0 Tx: 52365 Fax: +49 89 2399 - 4465	56 epmu d	one No. +49 89 2399-7851				

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IT 03/00214

1.	Basis	of	the	re	рo	rt
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1. With regard to the **elements** of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

	Des	cription, Pages					
	1-10)	as originally filed				
	Clai	ms, Numbers					
	1-15	5	as originally filed				
2.	With lang	ith regard to the language , all the elements marked above were available or furnished to this Authority in the nguage in which the international application was filed, unless otherwise indicated under this item.					
	The	se elements were ava	allable or furnished to this Authority in the following language: , which is:				
		the language of a tra	nslation furnished for the purposes of the international search (under Rule 23.1(b)).				
	the language of publication of the international application (under Rule 48.3(b)).						
		the language of a tra Rule 55.2 and/or 55.3	nslation furnished for the purposes of international preliminary examination (under 3).				
3.	With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:						
		contained in the inter	national application in written form.				
		filed together with the	e international application in computer readable form.				
		· · · · · · · · · · · · · · · · · · ·					
			tly to this Authority in computer readable form.				
		☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.					
		The statement that the listing has been furni	ne information recorded in computer readable form is identical to the written sequence shed.				
4.	The	amendments have re	esulted in the cancellation of:				
		the description,	pages:				
		the claims,	Nos.:				
	□ ,	the drawings,	sheets:				
5.		This report has been been considered to g	established as if (some of) the amendments had not been made, since they have go beyond the disclosure as filed (Rule 70.2(c)).				
		(Any replacement sh	neet containing such amendments must be referred to under item 1 and annexed to this				
6.	Add	litional observations, i	f necessary:				

INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No.

PCT/IT 03/00214

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Inventive step (IS)

No:

Yes: Claims

PARCAL

Claims

Claims

Yes: Claims

1-15

Industrial applicability (IA)

Yes: Claims

1-15

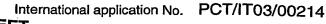
No: Claims

2. Citations and explanations

see separate sheet



INTERNATIONAL PRELIMINARY **EXAMINATION REPORT - SEPARATE SHEET**



Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- The documents cited in the International Search Report (ISR) are consecutively 1. numbered D1-D6 in the order of their listing. If not indicated otherwise, reference is made to the passages cited in said ISR.
- 2. The subject-matter of claims 1 to 15 is novel according to Art. 33(2) PCT, since the prior art does not describe the use of L-carnitine, acetyl L-carnitine and propionyl L- carnitine, all 3 in combination, for the treatment of oligoasthenospermia.
- The combined use of L-carnitine and acetyl-L-carnitine for the treatment of 3. oligoasthenospermia is known from D1.

It is also known from D2 that acyl L-carnitines, e.g. propionyl L-carnitine, are useful for the treatment of oligoasthenospermias.

According to the application (page 6, fifth paragraph) the combination of the three compounds would result in a significant increase of the sperm motility and concentration as compared to the combination of L-carnitine and acetyl-Lcarnitine.

However, in the absence of appropriate evidence (e.g. experimental data) showing that the present combination exerts a synergistic effect over the effect of the 3 single "carnitines" or over the combination of D1 and propionyl L- carnitine, an inventive step for the subject-matter of claims 1 to 15 cannot be acknowledged in the sense of Art. 33(3) PCT.